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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,527	12/27/2001	Raymond L. Houghton	210121.513C1	7914

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EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/033,527

Applicant(s)

HOUGHTON ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37,40,41 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37,40,41 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/15/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's amendment filed May 15, 2006 is acknowledged and has been entered. Claim 37, 40, 41, 44 and 46 have been amended. Claims 1-36, 38-39, 42 and 43 have been canceled. Claims 37, 40-41, 44-46 are pending and addressed in this Office Action. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

**This action is made FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. The objections to priority of provisional applications 60/219862, 60221300, and 60256592 are withdrawn upon further review of the instant application. The objection to provisional application 60/194,241 is maintained however, because the sequences elected therein are not found of record in the aforementioned provisional. The application is afforded the filing date of December 27, 2001.

### ***Previous Rejections***

4. The claim rejection under 35 USC 112 first paragraph is maintained and discussed below. The prior art rejections under 35 USC 102(b) are withdrawn in view of Applicant's amendment.

*Claim Rejections - 35 USC § 112*

5. **Issue: Claims 37, 40-41 and 44-46 are rejected under 35 USC 112 first paragraph as lacking enablement.**

*Applicant's traversal*

Applicant traverses the rejection on the following ground: Applicant summarizes the Examiner's rejection and states for the purpose of clarity and to advance prosecution of the subject application. Applicant has amended the claims to recite a composition for detecting a breast cancer cell in a biological sample. Applicant concludes that the subject matter is fully enabled.

*Examiner's Response*

All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow. While Applicant's amendment is acknowledged, the Examiner maintains that the claims are not enabled fully in scope. Applicant has not shown either that the nucleic acid molecules comprising SEQ ID NO: 7 and SEQ ID NO: 75 are expressed only in breast cancer tissue or that it has any pharmacological activity. The only fact Applicant has asserted with respect to SEQ ID NOS: 7 and 75 is that these sequences are associated with the B305D isoforms A and C and GABA $\pi$ . No further explanation has been provided in the specification regarding SEQ ID NOS: 7 and 75. Regarding B305D isoforms A and C, which also encompasses SEQ ID NOS: 1, 3 and 5-7, and GABA $\pi$ , which encompasses SEQ ID NO: 73-75 (see specification at page 40); the specification teaches that B305D are highly overexpressed in breast tumors, prostate tumors, normal prostate tissue and testis

compared to normal tissues, including normal breast tissue and GABA $\pi$  is overexpressed in lung, thymus, prostate at low levels and highly overexpressed in uterus. Applicant's tissue expression profiling data shows that B305D and GABA $\pi$ , in combination together, are capable of effectively detecting breast metastases and breast tumor cells. However, the level of expression of SEQ ID NO: 7 and 75 in cancer cells versus normal cells is unclear. No comparative levels of expression of SEQ ID NOS: 7 and 75 in cancerous cells versus normal cells as being indicative of tumorogenesis is given. In order for SEQ ID NOS: 7 and 75 to be diagnostic for breast cancer, its level of expression in breast cancer cells would have to be significantly higher than in normal breast cells as well as in other tissues and organs of the body. Applicant has not provided conclusive evidence that this is indeed the case. As noted in the prior Office action, while the art supports the fact that these sequences are overexpressed in breast tumor cells, there is no evidence of record or suggested in the art that the utilization of the SEQ ID NO: 7 and 75 corresponding to these breast tissues specific genes would be helpful in the diagnosis of cancers or breast cancers. Many proteins are highly expressed in normal tissues and diseases tissues. Therefore, one needs to know, e.g., that the claimed polynucleotides are either present only in cancer tissue to the exclusion of normal tissues or is expressed in *significantly* higher levels in diseased tissues *compared* to normal tissues (overexpression). Thus, undue experimentation is necessary to determine if there is a correlation between the claimed composition comprising SEQ ID NO: 7 and 75 and breast cancer. The examiner maintains that the claimed invention is not enabled fully in scope.

***Conclusion***

6. No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

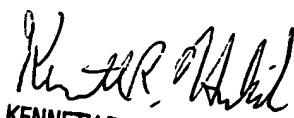
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER  
8/1/06